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David S. Resnick Nixon Peabody 100 Summer Street Boston, MA 02110-2131			MARX, IRENE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,868	TREMBLAY ET AL.	

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12/11/08 and 12/17/08.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6, 11 and 12 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-6, 11 and 12 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

The amendments filed 12/11/08 and 12/17/08 acknowledged. Claims 1-6 and 11-12 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 11-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for "specifically producing polyunsaturated acids" from all possible diatomaceous algae or for "producing specifically polyunsaturated fatty acids" from all possible diatomaceous algae. There is nothing in the as filed specification to indicate that this process is "specific" for a myriad of diatomaceous algae. Specificity is not found addressed in the instant written disclosure. In order words, there is no clear indication that "the step of applying at least one growth-limiting factor to a culture of diatomaceous algae at the end of the exponential growth phase" will result in the exclusive "stocking" of polyunsaturated fatty acids in all diatomaceous algae. In this regard, it is not disclosed in the present record how applicant is able to communicate to the diatomaceous algae that they are to "specifically" produce polyunsaturated fatty acids.

Insertion of the limitation "specifically producing polyunsaturated acids" from all possible diatomaceous algae or for "producing specifically polyunsaturated fatty acids" from all possible diatomaceous algae does not have support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of "specifically producing polyunsaturated acids" from all possible diatomaceous algae or for "producing specifically polyunsaturated fatty acids" from all possible diatomaceous algae. There are two examples in the specification, one using *Chaetoceros*

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gracilis and one using *Skelotonema costatum*. In each of these examples, the production of certain unsaturated fatty acids is **increased** manipulating the process conditions in a specific manner. This is not sufficient support for the new genus of limitation "specifically producing polyunsaturated acids" from all possible diatomaceous algae or for "producing specifically polyunsaturated fatty acids" from all possible diatomaceous algae or even from all *Chaetoceros gracilis* and *Skelotonema costatum*. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate possession of a concept after the fact. Thus, the insertion of "specifically producing polyunsaturated acids" from all possible diatomaceous algae or for "producing specifically polyunsaturated fatty acids" from diatomaceous algae is considered to be the insertion of new matter for the above reasons.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 and 11-12 are vague, indefinite and confusing in the recitation of "**specifically producing**" and "**producing specifically** polyunsaturated fatty acids". The intended meaning of this phrase is unclear in this context, even when interpreting the claim in light of the specification. See also the new matter rejection *supra*.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by McGinnis, *Journal of Applied Phycology* 9: 19–24, 1997 for the reasons as stated in the last Office action and the further reasons below.

The claims are directed to a method for "specifically" producing polyunsaturated fatty acids from diatomaceous algae, wherein at least one growth-limiting factor is applied at the end of the exponential growth phase, causing growth arrest and production of polyunsaturated fatty acids

McGinnis teaches a process of culturing diatomaceous algae wherein at least some of the diatoms were in exponential growth phase when growth limiting factors were applied, causing growth arrest and production of polyunsaturated fatty acids. See, e.g., page 20, col. 2, paragraph 2.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that McGinnis nowhere discloses a method for specifically producing polyunsaturated fatty acids as claimed. However, the present specification similarly nowhere discloses a method for specifically producing polyunsaturated fatty acids as claimed. In addition, the reference discloses substantially the same culturing steps to obtain the same product.

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In addition, applicant argues that at day four the alga is clearly in the "dormant" phase rather than at the "end of the exponential phase". However, all that the claim requires in that there is "at least one growth-limiting factor at the end of the exponential growth phase" in the medium. One of ordinary skill in the art would have recognized that culture growth for these algae is not synchronized, such that the algal cells are not all in the same identical growth phase at the same time. Moreover applicant has not indicated with any particularity the time at the "end of exponential phase" that the growth-limiting factor is to be applied or how the precise "end of exponential phase" is to be assessed for any and all diatomaceous algae.

The "end of exponential phase" does not provide precision as to the timing intended for the application of at least one-growth limiting factor. For example, the specification at [0016] indicates that after 6-7 days the algae cultured with at the end of their exponential phase.

Predictability is not an issue in anticipation rejections.

Therefore the rejection is deemed proper and it is adhered to.

Claims 4-5 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Dempster TA ((1994) Influence of environmental parameters on growth and lipid production in *Nitzschia communis*. M.S. Thesis, Arizona State University, 100 pp.) for the reasons as stated in the last Office action and the further reasons below.

The claims are directed to a method for "specifically" producing polyunsaturated fatty acids from diatomaceous algae, wherein at least one growth-limiting factor is applied at the end of the exponential growth phase, causing growth arrest and production of polyunsaturated fatty acids

Dempster teaches a process of culturing diatomaceous algae wherein at least some of the diatoms were in exponential growth phase when growth limiting factors were applied, causing growth arrest and production of polyunsaturated fatty acids. See, e.g., pages 33-42.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that Dempster nowhere discloses a method for specifically producing polyunsaturated fatty acids as claimed. However, the present specification similarly nowhere

discloses a method for specifically producing polyunsaturated fatty acids as claimed. In addition, the reference discloses the same culturing steps to obtain the same product. Regarding the showing of increase in production of polyunsaturated fatty acids in only one species, it is noted that applicant shows increased production in only two species and yet extrapolates to "specifically producing polyunsaturated fatty acids" in all diatomaceous algae.

Therefore the rejection is deemed proper and it is adhered to.

Claims 1, 3, 4 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Taguchi *et al.*, of record, for the reasons as stated in the last Office action and the further reasons below.

The claims are directed to a method for producing polyunsaturated fatty acids from diatomaceous algae, wherein at least one growth-limiting factor is applied at the end of the exponential growth phase, causing growth arrest and production of polyunsaturated fatty acids

Taguchi teaches a process of culturing diatomaceous algae wherein at least some of the diatoms where in exponential growth phase when growth limiting factors, such as silicate deprivation, were applied, causing growth arrest and production of polyunsaturated fatty acids. See, e.g., pages 260-267.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The Taguchi *et al.* reference applied, as correctly indicated by applicant, only has pages 260-267. The error and confusion is regretted.

Applicant's arguments to distinguish between "deprivation" and "exhaustion" by stating that silica has to be removed from the medium are noted. However, this argument fails to persuade because "exhaustion" also implies removal from the medium. Moreover, "removal" is not a step in the claimed method; all that the claim requires in that there is "at least one growth-limiting factor" "at the end of the exponential growth phase".

Applicant's argues that in Taguchi *et al.* the medium is not **actively** deprived of silica. However, all the claim requires is the step of "applying at least one growth-limiting factors". In the specification [0016] it is indicated that the algae are stressed by "depriving them of

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nutrients". How this step is "applied" is irrelevant in the context of arresting growth due to nutrient deprivation.

Therefore the rejection is deemed proper and it is adhered to.

Claims 1-6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGinnis *et al.* taken with Dempster and Taguchi *et al.*

The claims are directed to a method for specifically producing polyunsaturated fatty acids from diatomaceous algae, wherein at least one growth-limiting factor is applied at the end of the exponential growth phase, causing growth arrest and production of polyunsaturated fatty acids

McGinnis teaches a process of culturing diatomaceous algae wherein at least some of the diatoms where in exponential growth phase when growth limiting factors were applied, causing growth arrest and production of polyunsaturated fatty acids. See, e.g., page 20, col. 2, paragraph 2.

Dempster teaches a process of culturing diatomaceous algae wherein at least some of the diatoms are in exponential growth phase when growth limiting factors are applied, causing growth arrest and production of polyunsaturated fatty acids. See, e.g., pages 33-42.

The references differ from the claimed invention in that silicate deprivation is not disclosed. However Taguchi *et al.* teach the influence of silicate deficiency on lipid synthesis by diatoms. Taguchi *et al.* studied the effects of *Chaetoceros gracilis*, *Hanstzschia* and *Cyclotella* strains and shows the favorable effects of lipid accumulation, including, of course, polyunsaturated fatty acids, after exponential growth and growth arrest. See, e.g., Fig 1.

The process conditions discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of process conditions for optimization purposes identified as result-effective variables cited in the references would have been *prima facie* obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of McGinnis *et al.* and Dempster by culturing diatomaceous algae under various growth-limiting conditions including silicate deprivation, as suggested by the teachings of Taguchi *et al.* for the expected benefit of maximizing the content of lipids in the diatomaceous algae cultures, including polyunsaturated

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fatty acids known to be useful in the pharmaceutical industries as well as being nutritionally essential to organisms such as oysters, fish and shrimp which are important nutrient sources for humans.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that none of the references discloses a method for specifically producing polyunsaturated fatty acids as claimed. However, the present specification similarly nowhere discloses a method for specifically producing polyunsaturated fatty acids in all diatomaceous algae or even in specific species as claimed. In addition, the references as a whole disclose the same culturing steps to obtain the same product. Regarding the alleged enrichment of specifically, polyunsaturated fatty acids, and the lack of enablement in the references cited for a method of specifically increasing polyunsaturated fatty acids, such disclosure is also lacking in the instant specification. See also the new matter rejection *supra*.

Regarding the argument that demonstrating that the lipid content is increased does not necessarily mean that the polyunsaturated fatty acids content is increased, applicant has not shown on this record that the amount of polyunsaturated fatty acids in all diatomaceous algae is increased, which, in addition, is not the subject matter claimed. It must also be remembered that the process steps of culturing diatomaceous algae in the references and as claimed are substantially the same. Therefore, one of ordinary skill in the art would have reasonably expected at the time the claimed invention was made that substantially the same results would be obtained, in the absence of evidence to the contrary.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

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Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
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